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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/748,853	12/30/2003	Carl J. Wheeler	1530.0260002	6433

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
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WASHINGTON, DC 20005

EXAMINER

GRAFFEO, MICHEL

ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/748,853	WHEELER, CARL J.	
	Examiner	Art Unit	
	Michel Graffeo	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 64-90 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 64-90 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Status of Action***

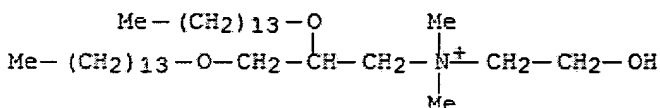
Examiner acknowledges Applicant's remarks filed 15 September 2006. Therein, Applicant remarks that the elected species, DMRIE, is not present in the Felgner reference. Applicant further identifies DMRIE as follows in the Restriction/Election requirement mailed 16 March 2006:

Applicant also provisionally elects the following species for initial search: DMRIE carboxylate propyl amide. This species is exemplified in Example 3. Claims 64 and 71 read on the elected species. With respect to this species, the variable groups of claim 64 are as follows: R_1 and R_2 are $\text{CH}_3(\text{CH}_2)_{12}\text{C}(\text{O})-$; R_3 and R_4 are CH_3 ; R_6 is propyl; Z is NR_1 , wherein R_1 is H; and n and m are 1. The variable groups of claim 71 are as follows: R_1 and R_2 are $\text{CH}_3(\text{CH}_2)_{12}\text{C}(\text{O})-$; R_3 and R_4 are CH_3 ; R_7 is H; R_8 is propyl; and n and m are 1.

During Examiner's search, the specie DMRIE was identified in Registry as such:

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L2 ANSWER 24 OF 30 REGISTRY COPYRIGHT 2006 ACS on STN
 RN 153312-64-2 REGISTRY
 ED Entered STN: 25 Feb 1994
 CN 1-Propanaminium, N-(2-hydroxyethyl)-N,N-dimethyl-2,3-bis(tetradecyloxy)-, bromide (9CI) (CA INDEX NAME)
 OTHER NAMES:
 CN **DMRIE**
 CN N-[1-(2,3-Ditetradecyloxy)propyl]-N,N-dimethyl-N-hydroxyethylammonium bromide
 DR 146659-77-0
 MF C35 H74 N O3 . Br
 CI COM
 SR CA
 LC STN Files: AGRICOLA, BIOSIS, CA, CAPLUS, IPA, MEDLINE, TOXCENTER, USPAT2, USPATFULL
 CRN (191980-81-1)



Confusingly, Applicant's definition and Examiner's interpretation of DMRIE are not the same and at the same time, neither Applicant's definition (Applicant's definition includes -C(O)- in the R1 and R2 radicals, which are not present in the claimed formula of claim 64) nor Examiner's are found in the instant claims. Therefore, the instant Restriction requirement is being mailed in response to which a species election is made which is present in the instant claims. Additionally, Applicant is reminded to elect a Markush species as outlined below in addition to a Group from I-IV and a species election.

Finally, in light of this new Restriction Requirement, the withdrawn status of claims 65-68,72-84 and 88-90 is removed so that claims 64-90 are now pending and Applicant may further re-evaluate their election.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 64-70 and 83-86, drawn to a method of delivering an anionic molecule into a cell comprising a compound classified in class 514, subclass 509.
- II. Claims 71-74 and 87-88, drawn to a method of delivering an anionic molecule into a cell comprising a compound classified in class 514, subclass 513.
- III. Claims 75-78 and 89-90, drawn to a method of delivering an anionic molecule into a cell comprising a compound classified in class 514, subclass 724.
- IV. Claims 79-82, drawn to a method of delivering an anionic molecule into a cell comprising a compound classified in class 514, subclass 529.

Inventions I and II are related as methods which share an alleged common utility of delivering an anionic molecule into a cell, but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, the products can be used to perform another utility such as for example in gene therapy.

Inventions I and III are related as methods which share an alleged common utility of delivering an anionic molecule into a cell, but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, the products can be used to perform another utility such as for example in gene therapy.

Inventions I and IV are related as methods which share an alleged common utility of delivering an anionic molecule into a cell, but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, the products can be used to perform another utility such as for example in gene therapy.

Inventions II and III are related as methods which share an alleged common utility of delivering an anionic molecule into a cell, but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be

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used to perform another utility. In this case, the products can be used to perform another utility such as for example in gene therapy.

Inventions II and IV are related as methods which share an alleged common utility of delivering an anionic molecule into a cell, but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, the products can be used to perform another utility such as for example in gene therapy.

Inventions III and IV are related as methods which share an alleged common utility of delivering an anionic molecule into a cell, but the common utility is not linked to a substantial structural feature. The products in this relationship are distinct if either or both of the following can be shown: (1) that the products encompass embodiments that are not required to perform the common utility or (2) that the products as claimed can be used to perform another utility. In this case, the products can be used to perform another utility such as for example in gene therapy.

Accordingly, Applicant is required to make an election of one of the Groups above and further, in addition, Applicant is required to make an election of one species therein as discussed below.

The practice, re: Markush claims encompassing multiple independent and patentably distinct inventions is set forth in M.P.E.P. 803. The following requirement to make a provisional election of a single independent and patentably distinct invention is made pursuant to said practice.

Claims 64-90 are drawn in Markush format encompass multiple and patentably distinct inventions. The claims are either drawn to different methods of delivering an anionic molecule to a cell. It is pointed out that the claims are directed to compounds which can include an amino acid, peptide, polypeptide, protein, nucleic acid, nucleotide, polynucleotide, mono, di- or polysaccharide, or other bioactive or pharmaceutical agent. Peptide containing compounds are classified in class 514 subclass 2 and are independent and distinct inventions from the Groups listed above.

The groups above are set forth in order of precedence in the claims. Any specie/compound/composition having the distinguishing feature set forth in one of the above groups will be contained in that group regardless of the fact that it may also contain a feature set forth in a group of lower precedence.

It is considered that a Markush type claim encompassing such species is directed to multiple independent and patentably distinct inventions since the species are so unrelated and diverse that a prior art reference anticipating the claims with respect to one of the species will not render the claim anticipated or obvious under 35 U.S.C. 102 nor 35 U.S.C. 103 respectively with regard to any one other of the species. Further these species are considered to be independent since they are unconnected in

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operation, one does not require the others for ultimate use and the specification does not disclose a dependent relationship between them. Moreover, each of the stated species is considered patentably distinct from the others on the basis of its properties. Thus, the stated species are capable of supporting separate patents under 35 U.S.C. 121.

Accordingly, applicants are required to make a provisional election of a single independent and /or patentably distinct Invention from Groups I-IV and further to elect an independent species of compound which either contains a amino acid, peptide, polypeptide, protein, nucleic acid, nucleotide, polynucleotide, mono, di- or polysaccharide, or other bioactive or pharmaceutical agent prior to an examination of said species on the merits.

Regardless of which invention Applicant elects, Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Specifically, applicant is required to define each of R^1 , R^2 , R^3 , R^4 , R^5 , R^6 , R^7 , n, m, Z and W and any additional variables as required for a particular species. In other words, Applicant must elect a specific compound and may provide a formula structure in lieu of the definitions of each variable. Currently, claims 64, 71, 75 and 79 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

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is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Election/Restrictions Proper

MPEP §809.02(d) states “[w]here only generic claims are presented, no restriction can be required except in those applications where the generic claims recite such a multiplicity of species that an unduly extensive and burdensome search is necessary.” Here, the claims recited such a multiplicity of species that an unduly extensive and burdensome search would be necessary if all of the claimed species were to be examined simultaneously.

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The present claims are directed to a method of treating respiratory complaints. Present claim 1 for example provides a variety of possibilities for R^1 , R^2 , R^3 , R^4 , R^5 , R^6 , R^7 , n, m, Z and W. For hypothetical exemplification purposes only, if each of the variables above were each limited to 10 possible moieties there would be 10^{11} possible species of compounds to be searched.

Further, as shown by the following classifications, a majority of the combinations encompassed by the present claims has acquired a separate status in the art. For example, if either R^3 or R^4 is a 7 membered ring containing one N it is classified in class 514 subclass 212.01, whereas if either R^3 or R^4 is a 6 membered ring containing one N it is classified in class 514 subclass 222.2. Notwithstanding that the classification of some of the active agents is co-extensive, all of the claimed compounds are patently distinct and fully capable of supporting separate patents.

For the above reasons, an election of a single disclosed species for examination purposes is deemed necessary and proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not

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distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michel Graffeo whose telephone number is 571-272-8505. The examiner can normally be reached on 9am to 5:30pm Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

16 February 2007
MG

 2/20/07
ARDIN H. MARSCHEL
SUPERVISORY PATENT EXAMINER